Presentation by

Mark Parrish, representing the
Healthcare Distribution Management Association
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Good afternoon Mr. Chairman and members of the Task Force and thank you for inviting me to participate in today's important roundtable.

My name is Mark Parrish and I am executive vice president of Cardinal Health, a healthcare product and services company. However, I am here today in my role as a member of the Board and Executive Committee of the Healthcare Distribution Management Association (HDMA).

HDMA is a national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication safely make their way to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States.

Since product integrity and patient safety are HDMA's most important priorities, I am honored to have this opportunity to highlight our perspectives on this extremely important study.

When considering importation, I think we can all agree that the most important consideration is to ensure patient safety. With that shared goal in mind, we believe there are two key areas that any approach to importation must address:

1. The first is product authentication. When our citizens order their medication, it must be assured they receive the drug in the exact specification their physician requires. This sounds simple, yet products are produced differently for different markets, based on differing standards. In addition to legal differences in same-brand-name pharmaceuticals, we know that counterfeiting is a much more pervasive criminal activity outside the United States and must protect against the effects of this insidious practice.
2. The second area is product integrity. When a patient is in need of a medication, there should never be a question about the strength or safety it possesses. We can not allow a system to be developed that does not properly address the multitude of factors that that cause degradation of pharmaceuticals.

There are significant challenges to ensure proper authentication and integrity of imported pharmaceuticals. Based on our experience, we would like to highlight several issues to be considered by this Task Force.

First, authentication. It must be assured that any imported drug is the U.S.-formulation of the product, made in a U.S.-approved manufacturing facility. To avoid any chance that an imported product is counterfeit, substandard, or otherwise unsuitable for U.S. patients, it is imperative to determine these two critical factors.

Product testing has been identified as a means to verify authenticity. But this method will fall short if tests don't consider both the active and inactive ingredients, which make up the total formulation of the drug. To ensure the imported drug is the U.S.-approved formulation made in a U.S.-approved plant requires either certification from the manufacturer or analytical testing for all the inactive ingredients. Similarly, the active ingredient would need to be certified, which would require comprehensive profiling of the imported product or certification from the manufacturer.

In addition, since we know that counterfeiting is a random event, to totally protect against counterfeit drugs from entering the U.S. market, every lot from every shipment would have to be tested, not just random samples. Considering the sophistication of the testing and the frequency with which it would have to be done, this would be costly.

While the challenge of authenticating imported supply is significant, the second area to address – Product Integrity – is perhaps even more complex and multifaceted.

The supply chain, both inside and outside the U.S., would need to be linear. This means product would have to flow from manufacturer to exporter to importer to pharmacy, in order to verify its authenticity. Moreover, there must be rigorous regulatory standards, registration requirements, and inspection programs specifically designed to ensure all those engaged in exporting and importing pharmaceuticals, including Internet pharmacies, are suitably qualified and possess the skills, infrastructure, and the interest to protect the integrity of the supply chain. Climate control, safe handling practices and strict adherence to manufacturer specifications are just a few of the important ways wholesalers protect the integrity of the U.S. drug supply.

In addition to product efficacy, the other key issue that must be addressed is product supply and demand. There will likely not be enough products to meet domestic demand under importation. U.S. pharmacists fill about ten times the number of prescriptions as are filled by their counterparts in Canada. An environment of strong demand, with low supply from Canada or other approved exporting countries, would open the door for transshipment of prescription drugs from other areas of the world and likely attract diverted, counterfeit, sub-potent and adulterated products

SUMMARY

In summary, with patient safety as our paramount goal, if a decision to move forward with importation is made, wholesalers -- with systems and infrastructures in place to protect product integrity and detect and deter counterfeit drugs -- would be best equipped to maintain the safety and security of the national drug supply.

As I said during my opening remarks, there are significant challenges that must be addressed to ensure the broad safety of imported products while maintaining the desired cost benefits for consumers. Should the FDA pursue importation, the two areas I have outlined today -- product authentication and integrity – must be thoroughly addressed. There are many other factors that will also need evaluation. I have focused my comments on the most significant.

Now, I would be happy to answer any questions you may have.